SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Drapolene Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drapolene contains:

Benzalkonium chloride solution	0.02% w/w
Equivalent to benzalkonium chloride	0.01% w/w
Cetrimide	0.2% w/w

Excipients with known effect:
Wool fat, cetyl alcohol, cetostearyl alcohol and chlorocresol.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream.
A smooth homogenous pink water miscible cream for topical application

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Drapolene is indicated for the relief of nappy rash and for use as an adjunct to baby care hygiene for the prevention of nappy rash.
Drapolene is indicated for the relief of urinary dermatitis in adults, and as an adjunct to patient care hygiene for the prevention of urinary dermatitis.
Drapolene is indicated for the symptomatic relief of minor burns, limited sunburn and the effects of weather.

4.2 Posology and method of administration

Posology:

Babies: The nappy area should be washed then dried thoroughly at each change of nappy. Drapolene Cream should be applied, paying particular attention to folds in the skin.

Adults: The affected area (or the area of application) should be washed and dried thoroughly before applying Drapolene. Regular routine application is advised.

Drapolene should be applied as required for minor burns, limited sunburn and the effects of weather.

Use in the Elderly: No special comment

Method of administration: Topical

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.
It is inadvisable to apply Drapolene Cream to a baby or adult who has an established hypersensitivity to benzalkonium chloride, cetrimide or wool fat (lanolin). Use should be discontinued if an allergic hypersensitivity reaction is suspected.

4.4 Special warnings and precautions for use

DRAPOLENE Cream is for external use only.

Not for application to mucosa.

Drapolene Cream contains wool fat (purified lanolin), cetyl alcohol and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) in some people.
Drapolene Cream also contains chlorocresol which may cause allergic reactions in some people.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

When used in accordance with the specified indications, systemic absorption of the specified components is not envisaged and so there are no special precautions/warnings appropriate to pregnancy and lactation.

You should not apply this medicine to the breasts if you are breast-feeding because the baby may take it in with your milk.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Allergic hypersensitivity reactions may occur in individuals who are sensitive to one or several components of Drapolene Cream.
Hypersensitivity to wool fat (lanolin) is recognised but is rare.
In a few individuals, benzalkonium chloride, used as a preservative in ophthalmic solutions, was associated with oedema and conjunctivitis.
Dermatitis as a result of contact allergy to benzalkonium chloride in plaster of Paris has also been reported.
Hypersensitivity to cetrimide is also known to occur, presenting as a localised contact dermatitis. In severe cases the rash may be generalised.

If the condition is aggravated, application should be discontinued and a healthcare professional consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

There are no reports of adverse events resulting from excessive application or accidental ingestion of Drapolene Cream.
In cases of accidental ingestion, symptomatic treatment is appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code; D08AJ01 and D08AJ04. ANTISEPTICS AND DISINFECTANTS /Quaternary ammonium compounds

Benzalkonium chloride and cetrimide are both quaternary ammonium antiseptics/disinfectants with properties typical of cationic surfactants. This preparation is useful in the treatment of and prevention of nappy rash, acting to suppress the development of ammonia producing organisms usually associated with this condition.

5.2 Pharmacokinetic properties

No data is available on the pharmacokinetics of the active ingredients of Drapolene Cream, when used for the specified indications. Systemic absorption of the active ingredients is not envisaged.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin and wool fat (purified lanolin) preblend
Cetyl alcohol
Emulsifying wax (contains cetostearyl alcohol)
Chlorocresol
Amaranth (E123)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

100g Tube - 48 months unopened.
500g PP pot with screw cap – 36 months unopened.
Other PP containers with snap-fit caps - 48 months unopened.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of container

25, 75, 150, 200 or 350 g - white pigmented polypropylene containers with white pigmented LDPE snap-fit caps or white pigmented polypropylene containers with white pigmented LDPE/HDPE snap-fit caps.
500 g polypropylene pots with PVDC faced wad and polypropylene screw caps.
100 g polyolefin/foil/polyolefin laminate tubes with polypropylene caps.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ravira Ltd,
Aiolou 4,
3020, Limassol, Cyprus

8. MARKETING AUTHORISATION NUMBER(S)

PL 44543/0001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/08/1989

10. DATE OF REVISION OF THE TEXT

April 2022